

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NORTHEASTERN DIVISION

UNITED STATES OF AMERICA,)
)
 Plaintiff,)
) No. _____
 v.)
)
 OAKLEY PHARMACY, INC., d/b/a)
 DALE HOLLOW PHARMACY; XPRESS)
 PHARMACY OF CLAY COUNTY, LLC;)
 THOMAS WEIR; MICHAEL GRIFFITH;)
 JOHN POLSTON, and LARRY LARKIN,)
)
 Defendants.) **UNDER SEAL**

DECLARATION OF SAMANTHA ROGERS

I, Samantha Rogers, declare under penalty of perjury that the following statements are true and correct:

Background

1. I am a diversion investigator for the Drug Enforcement Administration (“DEA”), in its Nashville District Office. I have been a diversion investigator since 2011. Before then I was an investigative assistant for the Gulf Coast High Intensity Drug Trafficking Area in the DEA’s Little Rock, Arkansas District Office.

2. In the course of my work as a diversion investigator I have been trained at the DEA’s Basic Diversion Investigator School in Quantico, Virginia. This was a 13 week course that teaches diversion investigators the body of federal law with which registrants under the Controlled Substances Act, 21 U.S.C. §§ 801, *et seq.* (the “CSA” or the “Act”), must comply. The course also trains diversion investigators in the practices and techniques DEA uses to determine whether registrants are in compliance with the CSA and the regulations promulgated under the CSA.

3. I have also attended the DEA's Advanced Diversion Investigator School, in Quantico, Virginia. This week long course teaches advanced techniques for inspecting registrants for compliance.

4. I have conducted or participated in well over 50 investigations of retail pharmacies over the past eight years.

Background and Facts Regarding Dale Hollow

5. On September 1, 2016, I was assigned to be the diversion investigator for Oakley Pharmacy, Inc. in Celina, Tennessee. Oakley Pharmacy, Inc. does business as a retail pharmacy, and is known alternatively as Dale Hollow Pharmacy ("Dale Hollow"). I inherited the case from another diversion investigator.

6. Celina, Tennessee is a small town in Clay County, Tennessee. Celina's population (according to 2017 Census Bureau records) is approximately 1,500. Clay county itself has a small population of approximately 8,000 (again according to 2017 Census Bureau records).

7. When I became the diversion investigator for Dale Hollow, I reviewed DEA's prior reports of investigation for the pharmacy. These reports of investigation are records made by DEA at or near the time of the events that these reports document by (or from information transmitted by) a person with knowledge, and kept in the ordinary course of DEA's regularly conducted activities.

8. Based on this review I learned the information that follows in this declaration about Dale Hollow.

9. Dale Hollow is a corporation formed and registered under the laws of the State of Tennessee, with its principal place of business in Celina in Clay County, Tennessee.

10. Defendant Thomas K. Weir is the majority owner (51%) and Chief Executive Officer of Dale Hollow and is a resident of Celina, Clay County, Tennessee. Weir operated, was a principal of, and exercised control over Defendant Dale Hollow.

11. John M. Polston is the pharmacist-in-charge of Dale Hollow and is licensed to practice pharmacy by the States of Kentucky and Tennessee. Under Tennessee law, as pharmacist-in-charge, Polston is “the supervisory pharmacist who has the authority and responsibility for compliance with laws and rules pertaining to the practice of pharmacy at the practice site of the pharmacist-in-charge.” Tenn. Code Ann. § 63-10-204(31). Defendant Polston is a resident of Tompkinsville, Kentucky.

12. On July 30, 2015, the Tennessee State Board of Pharmacy placed Polston on a two-year probation for giving early refills and dispensing controlled substances to a family member without a prescription.

13. During a June 14, 2016 interview, Polston acknowledged to DEA that some customers visit Dale Hollow in small groups to fill prescriptions for the same drug.

14. During the same June 14, 2016 interview, Polston told DEA investigators that he was concerned about activities taking place at Dale Hollow as well as Weir’s actions. According to Polston, Weir preferred for the pharmacy to order 17 bottles of buprenorphine per day to ensure they had sufficient supply and would never turn customers away. At the end of each day, Weir asked for total daily buprenorphine sales and the amount of buprenorphine in stock. Dale Hollow charged \$4 per buprenorphine pill at that time, and Polston said that Subutex and Suboxone (the buprenorphine formula with naloxone) accounted for approximately 60% of Dale Hollow’s controlled substance sales. Polston said that Weir sometimes asked him to fill controlled substance prescriptions one or two days earlier than the refill date. Polston said he felt he was in an awkward

position, because he did not want to jeopardize his employment or his license. Polston reported that Weir had told him that, if we get past this inspection, we are going to take this business to a whole new level.

15. During an October 2016 meeting with Weir, Polston, and DEA, Polston stated that there is a big drug abuse problem in their area and that many people are on buprenorphine products just to stay functional. Polston also said that he had seen an increase in gabapentin prescriptions and had heard they sold for \$15 per tablet on the street.

16. During the DEA's June 2018 inspection of Dale Hollow, Polston said that Dale Hollow charges \$5 for each Subutex (buprenorphine without naloxone) pill.

17. During an interview with a former employee of Dale Hollow in December 2018, DEA agents were told that Polston would regularly ask patients coming into Dale Hollow to fill controlled substance prescriptions to also fill non-controlled prescriptions. The former employee related that he thought that Polston did this to generate more revenue and to make the pharmacy look good in terms of the percentage of controlled versus non-controlled prescriptions it filled. Federal agents were also told that if a regular customer came in for an early fill on a controlled substance prescription and the former employee refused to fill the prescription, that former employee would often get a call from Polston to fill the prescription anyway.

18. Defendant Larry F. Larkin works as a part-time pharmacist for Weir at Dale Hollow and the other pharmacy Weir owns in Celina, Xpress Pharmacy of Clay County, LLC ("Xpress"). He is licensed to practice pharmacy by the State of Tennessee. He is a resident of Knoxville, Tennessee.

19. In 2004, Larkin entered into a consent order with the Tennessee Board of Pharmacy in which his pharmacy license was revoked due to his use of cocaine, benzodiazepines and alcohol.

Following his 2006 license reinstatement, in December 2008, Larkin entered into a second consent order with the Tennessee Board of Pharmacy in which he paid a \$500 fine due to allegations that he had mis-filled a patient's prescription.

20. In September 2016, Larkin spoke to DEA investigators. Larkin discussed some drug addicts who came to Dale Hollow to get prescriptions filled. He said that "we don't have to fill them, but we do." Larkin said that he would fill prescriptions a day early and that it was his right to do so. Regarding Xpress, Larkin said that people come in hoards to Xpress on Saturdays for Suboxone, since Dale Hollow was closed on Saturdays at that time. Larkin stated that he had heard that a lot of people are selling their pills and that the pharmacies' biggest sellers are oxycodone and gabapentin.

21. According to DEA data, between 2015 and 2018, Dale Hollow alone ordered enough morphine milligram equivalents of opioids from pharmaceutical distributors to provide almost one-and-a-half maximum-strength Vicodin pills every day to each man, woman, and child in Clay County.

22. I understand that there are approximately 68,000 community pharmacies in the United States. According to DEA data, only two of those 68,000 pharmacies purchased more opioid doses per capita than Dale Hollow over the last three years.

23. Dale Hollow, in 2016, purchased more buprenorphine — an opioid chiefly used to prevent withdrawal symptoms in those addicted to other opioids — than all but two pharmacies in the entire state of Tennessee. In 2017, Dale Hollow still ranked in the top 20 of buprenorphine purchasers in Tennessee.

24. Because buprenorphine is itself an opioid used to treat those dependent on opioids, like methadone, it is highly susceptible to abuse. To help safeguard against such abuse, in addition

to pure buprenorphine (brand name, Subutex), buprenorphine is also available in a formulation that contains naloxone as an anti-abuse component (brand name, Suboxone). Tennessee law requires that the monotherapy formulation (Subutex) may only be prescribed for a patient who is “pregnant; a nursing mother; or has a documented history of an adverse reaction or hypersensitivity to naloxone.” Tenn. Code Ann. § 53-11-311(b)(1).

25. It is my understanding that patients requiring monotherapy rather than the anti-abuse formulation are uncommon.

26. In fact, approximately 90% of buprenorphine prescriptions filled at Dale Hollow are for the monotherapy formulation; that is, pure buprenorphine without the anti-abuse safeguard.

27. Dale Hollow is currently registered as a retail pharmacy with DEA in Schedule II–V controlled substances under registration number FD2546197.

28. Dale Hollow was previously registered with DEA as Donaldson Pharmacy with a different registration number. That registration was surrendered in April 2011 after William Donaldson, then the pharmacy’s owner and pharmacist-in-charge, was indicted by a federal grand jury on five counts of illegal distribution of hydrocodone, a scheduled controlled substance. Donaldson subsequently pleaded guilty and was sentenced to fifteen months imprisonment in 2013.

29. Following the surrender of Donaldson’s DEA registration, Donaldson sold his stake in the pharmacy to his sister, Anne Oakley, who was granted a DEA registration for Oakley Pharmacy, Inc. d/b/a Dale Hollow pharmacy on or about April 28, 2011. Following Ms. Oakley’s death in 2015, her husband, Charles Oakley, owned the pharmacy in its entirety. Mr. Oakley then sold 51% of the pharmacy to Tom Weir.

30. In January 2016, the Tennessee State Board of Pharmacy (“BOP”) entered an agreed order signed by Weir on behalf of Dale Hollow. The order described numerous violations of Tennessee law and regulations governing the practice of pharmacy, and detailed how Dale Hollow staff admitted to, among other violations, dispensing early refills without documenting any necessity, failing to locate hard copies of controlled substance prescriptions for a family member of pharmacist-in-charge (Polston), and possessing bottles of medication from other pharmacies. The BOP suspended Dale Hollow’s pharmacy license for a period of five years, with a stay of the suspension for probation after finding that the pharmacy failed to comply with state pharmacy rules designed to protect the health, safety, and welfare of the public. Among the violations noted by the BOP was that the pharmacy failed to properly dispense controlled substances in a manner consistent with the laws governing the practice of pharmacy. The Tennessee Department of Health indicates that Dale Hollow’s state pharmacy license remains “on probation” to this day.

31. At approximately 12:48 a.m. on April 19, 2016, the Clay County Sheriff’s Office and Celina City Police responded to an alarm call at Dale Hollow. Upon arrival, the officers observed pill bottles laying on the floor near the front door of the pharmacy. When Weir arrived at the property, he said that the employees had probably put the pills there to sort them out and then yelled at the officer and refused to let him clear and secure the building. Weir refused to allow officers behind the pharmacy counter and ordered them to leave and to not return, stating that he “would rather someone steal everything than [have law enforcement] clear and secure the building.”

32. On or about May 6, 2016, the Sheriff of Clay County advised DEA investigators that Donaldson was continuing to work at Dale Hollow Pharmacy notwithstanding his prior criminal conviction pertaining to controlled substances from that same location.

33. On May 12, 2016, DEA inspected Dale Hollow because information showed that it was the second largest purchaser of buprenorphine in the DEA Nashville District Office coverage area in 2016, and the pharmacy had filled numerous prescriptions for customers who traveled long distances to have their prescriptions filled. During its inspection that day, DEA found several record-keeping violations, including the pharmacy's failure to account for several controlled substances. That inspection also caused DEA concern regarding the legitimacy of the pharmacy's dispensing practices, including the pharmacy's apparent filling of prescriptions despite the existence of several indicia of diversion and abuse associated with those prescriptions.

34. In October 2016, DEA confronted Weir with DEA's findings at the conclusion of the inspection and identified the various CSA violations that DEA had found at Dale Hollow. DEA also educated Weir and Dale Hollow's pharmacist-in-charge, John Polston, about its improper, early refills of controlled substance prescriptions. It also advised them not to fill prescriptions from patients who live far away from the pharmacy, and that Dale Hollow was in the top three pharmacy purchasers of buprenorphine in Tennessee.

35. In March 2017, as a result of DEA's inspection findings, the DEA and Dale Hollow entered into a memorandum of agreement that memorialized the deficiencies and DEA's concerns regarding what appeared to be violations of both federal and state law, and they formally set forth Dale Hollow's commitment to comply with its legal obligations, including with regard to buprenorphine dispensing. The agreement was executed by Weir as "CEO/Owner" of Dale Hollow, as well as by Polston, as "Pharmacist-in-charge." The agreement noted the CSA

discrepancies uncovered at Dale Hollow by the DEA and – in lieu of revoking Dale Hollow’s DEA registration number – memorialized Dale Hollow’s agreement that it would comply with the CSA and Tennessee State requirements, including “regulations pertaining to the dispensation of buprenorphine products for opioid addiction treatment.”

36. In June 2018, Polston admitted to DEA investigators that approximately 35% of the prescriptions at Dale Hollow are paid for in cash, and the cash payments are almost exclusively for controlled substances.

37. In June 2018 Polston further admitted that approximately 40% of the prescriptions filled at Dale Hollow are for controlled substances. DEA’s review of the pharmacy’s own dispensing records shows that on Saturdays, controlled substances account for up to 86% of all prescriptions filled at Dale Hollow.

38. In June 2018, DEA conducted a scheduled investigation of Dale Hollow. On the first day of that inspection, on June 12, 2018, Weir stated that he buys troubled business and turns them around. He said that doctors need to be investigated, since they are the ones writing prescriptions and that the pharmacist and pharmacies are not responsible because they only fill the prescription. Weir further said that he did not believe there is an opioid problem and that it is media hype. Regarding the DEA MOA, Weir said that he was badgered to sign it and that the DEA is out to get him. In addition, Weir said that he cannot tell a board certified doctor, “no.” Weir also remarked that pharmacies are like car lots, such that if you put several pharmacies together, business increases. On the final inspection date of June 14, 2018, Weir said that in his construction business, he knows guys that only function using Subutex (buprenorphine). Throughout the inspection, DEA investigators observed several customers show up multiple times, including several times in one day as well as on back-to-back days.

39. On June 19, 2018, DEA called Weir and asked him to surrender Dale Hollow's DEA registration number, but Weir declined to do so.

40. In late July, 2018, I served Dale Hollow with a DEA records subpoena for hard copy prescriptions and for copies of prescription dispensing profiles for Dale Hollow patients to whom the pharmacy dispensed controlled substances from January 2017 through July 2018.

41. In late August 2018, I served Dale Hollow with an Administrative Inspection Warrant. During the August 2018 inspection, pharmacist-in-charge John Polston told me that to the extent that pharmacists at Dale Hollow noticed and investigated facts indicating potential abuse or diversion of controlled substances (red flags) in the prescriptions they filled, the pharmacists would document what they noted either on the hard copy of the prescription itself or in the pharmacy's patient profile on its computer system. With this in mind, DEA obtained an image of the pharmacy's computer system on which it stored patient profiles.

42. After the inspection, I gathered Tennessee Controlled Substance Monitoring Program: RX History Reports ("CSMD reports") and the pharmacy's patient dispensing histories for some of the patients who appeared to present prescriptions with red flags of diversion.

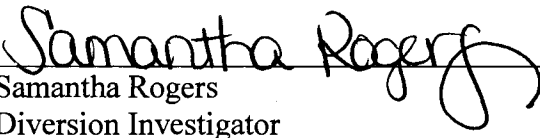
43. I provided those materials to Dr. Carl Gainor, a pharmacist and professor of pharmacy, for his review and opinion.

44. More recently, I obtained updated CSMD reports for the patients whose prescriptions I sent to Dr. Gainor. These CSMD reports disclosed that the majority of the patients whose records I sent to Dr. Gainor continue to have controlled substance prescriptions filled at Dale Hollow as late as January and February 2019.

45. I also reviewed CSMD reports for all of 2018, which show that Dale Hollow filled at least 10,000 controlled substance prescriptions in 2018.

46. During a December 2018 interview with a former employee of both Dale Hollow and Xpress, the former employee disclosed that on one occasion after she had refused to fill a prescription for Percocet early, Weir called her and directed her to fill the prescription early because the patient was a good customer.

Executed on February 7, 2019.


Samantha Rogers
Diversion Investigator
Drug Enforcement Administration
Nashville District Office